

EXHIBIT 26

4-85

50 No. 101  
21417-21580

Friday  
May 24, 1985

## Selected Subjects

### Administrative Practice and Procedure

Customs Service  
Interior Department  
Social Security Administration

### Aid to Families With Dependent Children

Social Security Administration

### Animal Diseases

Animal and Plant Inspection Service

### Animal Drugs

Food and Drug Administration

### Authority Delegations (Government Agencies)

Federal Energy Regulatory Commission

### Bilingual Education

Education Department

### Cargo Vessels

Customs Service

### Customs Duties and Inspection

Customs Service

### Exports

International Trade Administration

### Fisheries

National Oceanic and Atmospheric Administration

### Freedom of Information

National Archives and Records Administration

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excluded under Federal laws other than the Social Security Act. (See the appendix to this subpart.)

6. The authority citation for Subpart L of Part 416 reads as follows:

Authority: Secs. 1102, 1601, 1602, 1611, 1612, 1613, 1614(f), and 1631(d) of the Social Security Act, as amended; 49 Stat. 647, as amended; 86 Stat. 1485, 1486, 1488, 1470, 1473; 42 U.S.C. 1302, 1381, 1381a, 1382, 1382a, 1382b, 1382c(f), and 1383(d), unless otherwise noted.

7. Section 416.1201 is amended by revising the last sentence in paragraph (a) to read as follows:

§ 416.1201 **Resources; general.**

(a) *Resources; defined.* \* \* \*

In addition, support and maintenance assistance not counted as income under § 416.1157 are not considered resources.

[FR Doc. 85-10941 Filed 5-23-85; 8:45 am]

BILLING CODE 4190-11-M

## Food and Drug Administration 21 CFR Ch. I

[Docket No. 85N-0214]

### The Drug Price Competition and Patent Term Restoration Act of 1984; Establishment of a Public File and Request for Comments

**AGENCY:** Food and Drug Administration.  
**ACTION:** Request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a docket containing a public record of the comments, views, and other information submitted to the agency from interested persons concerning Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and is inviting public comment on interpretation of the statute for purposes of the agency's regulation writing process.

**DATE:** Comments on Title I of Pub. L. 98-417 by July 8, 1985:

**ADDRESS:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Marilyn L. Watson, Center for Drugs and Biologics (HFN-380), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3640.

## SUPPLEMENTARY INFORMATION:

### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) was signed into law September 24, 1984. The new law consists of two titles that concern generic new drugs. Title I of the new law, which amends section 505 of the Federal Food, Drug, and Cosmetic Act, codifies FDA's authority to accept abbreviated new drug applications (ANDA's) for generic versions of drug products first approved after 1962. Prior to the enactment of Pub. L. 98-417, ANDA's were permitted under FDA regulations for generic versions of drug products first approved between 1938 and 1962. Title I also addresses filing and approval requirements for paper NDA's.

Title II of Pub. L. 98-417 amends the patent law to provide for the extension of the normal 17-year term of a product, use, or process patent of a patented product which is subject to premarketing clearance. In a future issue of the *Federal Register*, FDA will publish a similar notice concerning the establishment of a public file, and a request for comments, on Title II.

### II. Public Record

FDA has established in the Dockets Management Branch, under Docket No. 85N-0214, a public file for all comments, views, and other information submitted to FDA concerning Title I of Pub. L. 98-417. Received comments will be incorporated into this public file and may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

### III. Public Comment

Section 105(a) of Pub. L. 98-417 requires FDA to promulgate implementing regulations. The new law is detailed and complex so that questions, identification of policy issues, and suggested interpretations of the new law by interested persons in the early stages of implementation of the law will assist FDA in developing these regulations in a timely fashion. Accordingly, FDA is inviting the submission of comments, views, or other information to assist the agency in its efforts to develop regulations implementing Title I of Pub. L. 98-417.

Interested persons may submit written comments on Title I of Pub. L. 98-417 to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets the heading of this document. To assure consideration of comments by FDA in developing the proposed regulations, comments on Pub. L. 98-417 should be submitted on or before July 8, 1985.

FDA has received comments and recommendations on Pub. L. 98-417 from the Pharmaceutical Manufacturers Association (PMA) and has placed the comments in the public file established by this notice. FDA invites comment on the PMA's submission.

Dated: May 17, 1985.

Mervin H. Shumate,  
Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 85-12537 Filed 5-23-85; 8:45 am]  
BILLING CODE 4160-01-M

## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

### 30 CFR Part 216

### Production Accounting and Audit System Regulations; Extension of Comment Period

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** This Notice extends the comment period from May 31, 1985, June 17, 1985, on the proposed rule concerning the information collection requirements necessary to verify the mineral production quantities have reported and used in calculating royalties due the Government from Federal and Indian leases. This proposed rule was published in the *Federal Register* on April 1, 1985 (50 FR 12828). The extension of the comment period is in response to requests received from the public to allow additional time for comment.

**DATE:** Comments by June 17, 1985.

**ADDRESS:** Comments should be mailed or delivered to Mr. Orie L. Kelm, Chief Office of Royalty Regulations,